

**REMARKS**

The Office Action of August 23, 2002 presents the examination of claims 1-2, 8-17, and 26. Claims 2-7 and 18-28 are canceled. Claims 1 and 8 are amended. No new matter is added to the application.

***Election/Restriction***

The Examiner withdraws from consideration claims 27 and 28, which were added in the Reply filed on May 24, 2002. Claims 27 and 28 are canceled, thus rendering the restriction requirement moot.

***Priority***

The Examiner maintains the objection to the Declaration. In order to overcome the objection, Applicants submit herewith a Supplemental Application Data Sheet under 37 C.F.R. § 1.76(c), which includes the foreign priority information. A Supplemental Application Data Sheet may be supplied prior to payment of the issue fee and serves to update information in a previously submitted oath or declaration under 37 C.F.R. § 1.63. Thus, the instant objection is overcome.

***Rejection under 35 U.S.C. § 112, first paragraph***

The Examiner rejects claims 1-2, 8-17, and 26 under 35 U.S.C. § 112, first paragraph for an alleged lack of enablement.

Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

*(1) Enablement of any joining peptide*

The Examiner maintains her position that any joining peptide of from 5 to 18 amino acids is not enabled by the specification. Applicants amend claim 1 to recite that the B and A chains are human insulin chains and that the joining peptide comprises the sequence of SEQ ID NO:1. On page 3, lines 7-12 of the Office Action, the Examiner states that the specification is enabling for a single-chain insulin analog wherein the B and A chains are human insulin chains and X has a sequence of SEQ ID NO:1. Thus, the rejection is overcome.

*(2) The enablement of any polypeptide*

The Examiner maintains the assertion that any polynucleotide encoding a single-chain insulin analog (SIA), as encompassed by the claims, is not enabled by the specification. Applicants amend claim 8 to recite that the polypeptide comprises the sequence of SEQ ID NO:3. On page 3, lines 16-19 of the Office Action, the Examiner states that the specification is enabling for a polynucleotide comprising the nucleic acid sequence of SEQ ID NO:3 that encodes a single-chain insulin analog. Thus, the rejection is overcome.

***Summary***

Applicants respectfully submit that the above amendments and remarks address and overcome all of the Examiner's rejections of record. Therefore, all of the present claims define patentable subject matter such that this application should be placed into condition for allowance. Early and favorable action of the merits of the present application is thereby respectfully requested.

If there are any minor matters precluding allowance of the application which may be resolved by a telephone discussion, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at (703) 205-8000.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of one (1) month to December 23, 2002 in which to file a reply to the Office Action. The required fee of \$110.00 is enclosed herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional

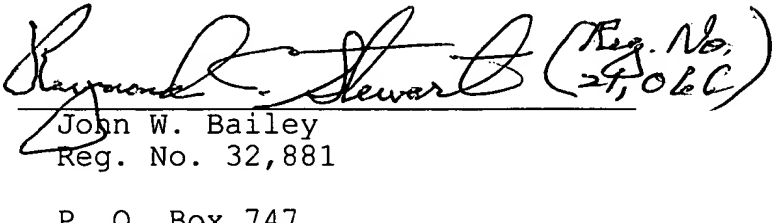
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fees required under 37 C.F.R. §§1.16 or 1.17; particularly,  
extension of time fees.

Respectfully submitted,

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Attachment:

Version with Markings to Show Changes Made

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claims 2-7 and 18-28 are deleted.

The following claims are amended:

1. (Amended) A single-chain insulin analog compound of formula (I) having the properties of greater insulin receptor binding activity than proinsulin and less insulin receptor binding activity than insulin:

B chain - X - A chain (I)

wherein:

B and A chains are the human insulin chains, respectively[, or functional analogs thereof]; and

X is a joining peptide comprising the following sequence:

Gly-Gly-Gly-Pro-Gly-Lys-Arg (SEQ ID NO:1) [of from 5 to 18 amino acids].

8. (Amended) A polynucleotide comprising the nucleic acid sequence of SEQ ID NO:3 that encodes [encoding] the single-chain insulin analog according to claim 1.